UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LONDON DIVISION

AMY FOISTER, et al.,	)	
	)	
Plaintiffs,	)	Civil Action No. 6:01-268-DCR
	)	
V.	)	
	)	
PURDUE PHARMA, L.P., et al.,	)	**JUDGMENT**
	)	
Defendants.	)	

** ** ** ** **

The Court having granted summary judgment in favor of the defendants and all claims asserted against them in this action having been dismissed, with prejudice, judgment is hereby entered in favor of the defendants and they are awarded all taxable costs incurred herein.

This is a final and appealable Judgment and there is no just cause for delay.

This 30th day of December, 2003.

Signed By:
Danny C. Reeves DCR
United States District Judge

EXHIBIT
2

197

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AMY FOISTER, et al.,	)	
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Plaintiffs,	)	Civil Action No. 6:01-268-DCR
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V.	)	
	)	
PURDUE PHARMA, L.P., et al.,	)	**MEMORANDUM OPINION**
	)	**AND ORDER**
Defendants.	)	

** ** ** ** **

This action involves claims by a number of plaintiffs (both individuals and representatives of estates) who assert that they have been harmed by OxyContin® ("OxyContin"), a pain-relieving drug manufactured by the Purdue defendants ("Purdue") and marketed by defendant Abbot Laboratories, Inc. ("Abbott"). While the use of OxyContin by some plaintiffs began legitimately, others abused the drug from the outset and in a manner that was clearly contrary to the instructions of their prescribing physicians. And although a variety of factual scenarios are presented, a number of facts are common to all plaintiffs and are dispositive.

This matter is presently before the Court for consideration of the motions for summary judgment filed by defendants Purdue Pharma L.P., The Purdue Frederick Company and Purdue Pharma Inc. [Record Nos. 125, 127, 148, 159, 162, 163] A separate motion for summary judgment has been filed by Abbott. [Record No. 132] In some cases, the plaintiffs' attorneys attempted to dismiss several claims from this action. Being unsuccessful in this endevor, they

194

then conceded that summary judgment should be entered against their clients, but ultimately disagreed with the manner of its entry. They argue that the Court should enter judgment without opinion or analysis of the parties' respective positions. To do more, they claim, would exceed the Court's jurisdiction.[1] In other instances, the plaintiffs oppose the requested relief.

In opposing these motions, the plaintiffs would have the Court abandon reason and common sense and fall prey to passion and prejudice against the defendants. In essence, the plaintiffs would have the Court ignore their own abuses as well as the warnings and instructions provided by the defendants and by other third party intermediaries. This Court, however, will not accept the plaintiffs' "victimization" mentality. For the reasons discussed herein, the Court will grant the motions for summary judgment in favor of the defendants and dismiss the claims of all plaintiffs in this action.

I. BACKGROUND

OxyContin is a prescription narcotic intended to help individuals with moderate to severe pain. It contains oxycodone, an opiate analgesic, as well as hydrochloride salt. OxyContin comes in 10, 20, 40, 80, and 160 milligram strength. The 80 mg. and 160 mg. pills are suitable only for opioid tolerant patients. Due to its opioid character, OxyContin is designated as a Schedule II controlled substance by the Food and Drug Administration ("FDA"). Thus, it is illegal to use or sell OxyContin without a valid prescription. 21 U.S.C. § 843(a); KRS § 218A.1415.

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[1] This argument is simply without merit. As the Court advised the parties during the hearing held in this action on December 12, 2003, where, as here, issues are properly presented for resolution, it this Court's duty and responsibility to address them.

Opioids have long been considered useful drugs for pain treatment. P. Tough, *The Alchemy of OxyContin*, N.Y. Times, July 29, 2001, § 6 (Magazine), at 32. At the same time, however, they have the potential to be highly-addictive. And like any narcotic medication, opioids are subject to abuse if not used as prescribed.

In the 1980's and 1990's, a growing movement to liberalize the use of opioids arose in response to the plight of cancer patients beset by extreme pain. *Id.* In 1994, the Department of Health and Human Services issued clinical guidelines encouraging the use of opioids to treat pain in cancer patients. *Id.* A year later, the FDA approved the use of OxyContin to treat moderate and severe pain. *Id.* Much of the drug's success was due to its time-release function: the pill is designed to release oxycodone in controlled amounts in order to keep the brain from receiving too much oxycodone. This time-release function reduced the likelihood that a patient would experience a euphoric high, as well as reducing the potential for addiction. *Id.*

Unfortunately, some patients as well as other individuals soon figured out that crushing the tablets would defeat the time-release function. By crushing the pills, these individuals were able to unlock the full narcotic effect of the oxycodone. *Id.* As word of this procedure spread, abuse of OxyContin proliferated. Abuse of the drug in this manner has been particularly problematic in remote, rural areas such as Eastern Kentucky. Such areas have become a breeding ground for OxyContin abuse because

> they're home to large populations of disabled and chronically ill people who are in need of pain relief; they're marked by high unemployment and a lack of economic opportunity; they're remote, far from the network of Interstates and metropolises through which heroin and cocaine travel; and they're areas where prescription drugs have been abused -- though in much smaller numbers -- in the past.

Id.

As discussed below, the plaintiffs used OxyContin at various times for both legitimate and illegitimate purposes. They now complain that they were harmed by their use of OxyContin. All purportedly suffered serious and debilitating side effects; namely, addiction to the drug.[2] Two claim that their relatives were killed by OxyContin. They allege, *inter alia*, that Purdue did not adequately warn them of the side effects.

A. Michael L. Daniels

Michael Daniels ("Daniels") is a 35-year old resident of Harlan County with an extensive history of abusing illegal drugs and prescription medications.[3] (Daniels Depo. at 14-22.) At the time of his deposition, Daniels was incarcerated in Tennessee for a felony charge of theft over $1,000 (stolen vehicle). While the result of this charge is unknown and of no consequence in this proceeding, his history of drug use and abuse is relevant.

Daniels abuse of prescription medications began at the age of 16. (Daniels Depo. at 15-16.) His drug history includes use and abuse of marijuana, Percocet,[4] Percodan,[5] Tylox,[6]

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2 Plaintiff Foister has attempted to re-characterize her injury as one related to "withdrawal symptoms." The Amended Complaint, however, speaks of her alleged addiction. (Amended Comp. at § 2, ¶ 1.) Regardless, Foister's alleged "withdrawal" symptoms were present *prior* to her use of OxyContin. (Foister Depo. at 65-68; Record No. 168, Ex. 6.)

3 Daniels also has an extensive criminal history. (Daniels Depo. at 9-12.) He has a pending charge in Harlan County, Kentucky, for trafficking Lorcet (a prescription drug). (Daniels Depo. at 12.)

4 Percocet is a Schedule II narcotic containing oxycodone and acetaminophen.

5 Percodan is a Schedule II narcotic containing oxycodone and aspirin.

6 Tylox is a Schedule II narcotic containing oxycodone and acetaminophen.

Roxanol,[7] cocaine, and methamphetamine. (Daniels Depo. at 14-21.) Daniels obtained his first OxyContin pill from a drug dealer in 1998. (Daniels Depo. at 24-26.) He utilized the following procedure to ingest his first pill:

> I'd just . . . lick the coating off of them, bust them off, buy a bottle of water and pour it in a cap, and I'd just draw up seven units of water and throw on it, take it back to the rig and work it up, and take a piece of cotton off the filter and put it on the needle and filter it, draw it up and hit it.

(Daniels Depo. at 27.) Thus, after modifying the pill he would ingest it intravenously, rather than take it orally. Between 1998 and 1999, Daniels purchased OxyContin on a daily basis and injected it in this manner. (Daniels Depo. at 30.) In fact he never took the medication as intended.

In 2000, Daniels obtained a prescription for OxyContin from Dr. Ali Sawaf (a recently-convicted felon). After Daniels had trouble getting Kentucky pharmacies to fill the prescriptions, Dr. Sawaf allowed Daniels to come to his office after hours to illegally obtain OxyContin pills.[8] (Daniels Depo. at 29.)

B. Robin D. Griffin

Robin Griffin ("Griffin") is a 29-year old housewife with a history of illegal drug use. She began using marijuana in high school. (Griffin Depo. at 35-36, 49.) Eventually, Griffin

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[7] Roxanol is a Schedule II narcotic containing morphine.

[8] Dr. Ali Hadi Sawaf was convicted in 2002 for prescribing OxyContin without a legitimate medical purpose. He received a 20 year sentence and his medical licence was suspended. *See United States v. Sawaf*, U.S. Dist. Ct., E.D. of Ky., Pikeville Div., No. 01-0047-KKC (Judgment entered August 27, 2002).

began using cocaine, acid, methamphetamine, Lorcet,[9] Lortab,[10] and Tylox. (Griffin Depo. at 35-38, 41, 66-67.) She has abused oxycodone-based drugs for years, and although she claims to prefer OxyContin, she will use any similar narcotic she can acquire. (Griffin Depo. at 37, 68-69.) In 1996, Griffin underwent treatment to break her of her addiction to Tylox. However, after three months of successful treatment, she resumed using the substance. (Griffin Depo. at 38, 40, 49-51.)

Griffin first sought OxyContin due to her affinity for Tylox. She found that the "high" from Tylox no longer satisfied her and discovered that OxyContin contained more oxycodone than Tylox. (Griffin Depo. at 45-48.) Therefore, she duped her physician into believing she was suffering from back pain and obtained a prescription for OxyContin. From the outset, Griffin misused the product by crushing and snorting the pills in order to get high. (Griffin Depo. at 55-57, 68.) Within a year, she found herself unsatisfied with the high from crushing and snorting OxyContin and began liquefying the pills and injecting the liquid intravenously to get a faster high. (Griffin Depo. at 54-55.)

Griffin admits that before ever taking OxyContin, she was well-aware of the warning against crushing and snorting the medication. Further, Griffin at no time used the drug in the manner prescribed by her doctors. (Griffin Depo. at 30) And at all relevant times, she acknowledged that she knew that misusing OxyContin could result in harm to her. (Griffin Depo. at 58-59.)

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[9] Lorcet is a Schedule III narcotic containing hydrocodone and acetaminophen.

[10] Lortab is a Schedule III narcotic containing hydrocodone and acetaminophen.

C. James P. Craig

James Craig ("Craig") is a 56-year old resident of Pathfork, Kentucky. He received his first prescription for OxyContin in October 1999 by a doctor in Virginia. The medication was prescribed to alleviate arthritis and back pain. (Craig Depo. at 21.) Soon thereafter, Craig began taking three pills a day instead of the two prescribed by his doctor. (Craig Depo. at 24, 51-53.) When three OxyContin pills did not satisfy him, Craig began crushing and snorting the pills after some drug-abusing friends clued him to the technique. (Craig Depo. at 24-26.) Although he was aware that this procedure was not recommended, his "friends" told him that crushing OxyContin made it twice as good. (Craig Depo. at 26.)

Only two months after receiving his initial prescription, Craig was taking between three and seven pills a day. (Craig Depo. at 53-54.) On a "usual day," Craig would take four pills, crushing and snorting some and taking some orally. (Craig Depo. at 53, 55-56.) As Craig's prescription supply could not support his abusive habit, Craig resorted to buying OxyContin illegally after he stopped receiving prescriptions for the medication in November of 2000. (Craig Depo. at 29, 39-40, 54.)

D. Rodney Howard

Rodney Howard ("Howard") is 30 years of age and is also a resident of Pathfork, Kentucky. After working for six years in the coal mines and two years operating a logging business, Howard became gravely ill with Crohn's disease. (Howard Depo. at 9-10, 15.) His

pain is severe and his prognosis is grim. In treating his pain, Howard has been prescribed Lorcet, Tylox and Demerol[11].

Howard was first prescribed OxyContin in January 2000. A month later, he began ignoring his doctor's order to take only two pills a day and began increasing his dosage. (Howard Depo. at 22, 28.) By March of that year, he was taking OxyContin orally every 60 to 90 minutes. (Howard Depo. at 28-29.) Around that time, Howard began crushing the pills and taking them intravenously through a portacath that had previously been inserted into his chest to assist in the administration of Demerol. (Howard Depo. at 32-33, 40.) When his doctor discovered that Howard had been injecting OxyContin in this fashion, the doctor ordered the portacath removed. [Record No. 149, Ex. 12]

Howard informed his doctor that the 20 mg. pills were not working, so the doctor increased his dosage to 40 mg. pills. (Howard Depo. at 24-25.) Howard took these pills intravenously, taking seven or eight pills each day. (Howard Depo. at 25, 39.) Soon thereafter, he complained to his doctor that the 40 mg. pills were not working, so the doctor prescribed him 80 mg. pills. (Howard Depo. at 39-40.) Howard injected these pills intravenously as well. (Howard Depo. at 39-40.)

When Howard's heavy pill habit could not be supported by his prescriptions, he purchased most of his pills illegally. (Howard Depo. at 48-50, 54.) He claims to buy as much as 400-500 mg. of OxyContin per day. (Howard Depo. at 54.) Howard's deposition testimony

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[11] Demerol is a Schedule II narcotic containing meperidine.

also suggested that he sells OxyContin, although he did not explicitly admit to doing so. (Howard Depo. at 48.)

E. George A. Saylor

George Saylor ("Saylor") sustained a back injury while working in the coal mines in 1998. (Saylor Depo. at 47.) To treat his pain, doctors initially tried a variety of medications, including Lorcet, Lortab, Percocet, and Tylox. (Saylor Depo. at 27-28.) When those medications because insufficient, he was prescribed OxyContin. Saylor received his first prescription in September 1998. [Record No. 160, Ex. 1] In June 1999, Saylor forged an OxyContin prescription, increasing the dosage from 10 mg. to 40 mg. [Record No. 160, Ex. 8] The pharmacy, however, refused to fill the prescription and his doctor refused to write him further prescriptions. [Record No. 160, Ex. 8]

Saylor abruptly stopped taking OxyContin sometime in late 1999 or early 2000. (Saylor Depo. at 62, 69.) After several days, he believed this was a mistake and thereafter decided to illegally purchase more OxyContin. (Saylor Depo. at 63.) He purchased $1,000 worth of OxyContin and chewed the pills to defeat the time-release mechanism. (Saylor Depo. at 67.) Thereafter, Saylor exclusively chewed or snorted the drug. (Saylor Depo. at 52, 72.) Eventually, he added intravenous injection to his repertoire of drug administration. (Saylor Depo. at 72.) Around this time he began chewing or snorting between five and six pills a day. (Saylor Depo. at 78.)

To meet his five to six pill a day habit, Saylor was forced to purchase the drugs illegally. In addition to purchasing OxyContin from drug dealers, Saylor also engaged in "doctor

shopping," *i.e.*, simultaneously receiving OxyContin prescriptions from multiple doctors without advising them of the other prescriptions. (Saylor Depo. at 55, 57.)

F. Johnny J. Wynn

Johnny Wynn ("Wynn") died on October 25, 2000 following an extended period of pain medication use and abuse facilitated by doctor shopping. Suit was brought on his behalf by his wife and the administratrix of his estate, Jerrie Ann Tollover Wynn.[12] She claims that his death was caused by OxyContin. Wynn began taking pain medications in 1994 following a back injury sustained at work. To help alleviate his pain, he was prescribed Lorcet and Hydrocodone APAP[13]. [Record No. 163, Ex. 5]

In the summer of 1994, Wynn engaged in doctor shopping to receive prescriptions for an excessive amount of Lorcet. [Record Nol. 163, Exs. 4, 5, 6] Wynn regularly took more Lorcet than he was prescribed. (Wynn Depo. at 51.) In fact, he would take between six and eight muscle relaxants at a time, then dissolve between 20 and 21 Lortab pills in a glass and drink the potent mixture in order to get high. (Wynn Depo. at 52.)

Sometime in 1997, Wynn obtained his first OxyContin prescription from the Lexington Pain Clinic in Lexington, Kentucky. (Wynn Depo. at 48-49, 50, 54, 87-89, 113.) Within two weeks of starting the prescription, Wynn took more than he was prescribed and chewed the pills. Wynn satisfied his OxyContin habit by illegally purchasing the pills from drug dealers. (Wynn

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[12] Jerrie Wynn has asserted claims as the statutory guardian and next friend of her children, Jamie William Wynn and Johnny Wynn, Jr. In addition, she has asserted claims for loss of parental and spousal consortium. For the reasons discussed herein, all claims will be dismissed with prejudice.

[13] Hydrocodone APAP is a Schedule III narcotic containing hydrocodone and acetaminophen.

Depo. at 71-72.) Eventually, Wynn began taking 12 to 14 pills a day. (Wynn Depo. at 115-16.) Wynn had his teeth pulled by his dentist in order to get prescriptions for Lortab and Lorcet, which he sold to finance his OxyContin habit. (Wynn Depo. at 94-98.) He also obtained OxyContin by having his wife lie to doctors about her physical condition in order to get OxyContin prescriptions which were then given to Wynn. (Wynn Depo. at 65-68, 77.)

Wynn's wife claims that his death was caused by OxyContin. However the death certificate and toxicology reports indicate otherwise. The death certificate lists the cause of death as "Acute Drug (Hydrocodone) Toxicity" [Record No. 163, Ex. 1] and the toxicology reports states that at the time of his death Wynn had hydrocodone and acetaminophen in his system. Hydrocodone and acetaminophen are the ingredients of Lorcet and Lortab; OxyContin does not contain these ingredients. Moreover, Wynn had not taken OxyContin for over a month before his death. [Record No. 163, Ex. 20]

In summary, it is clear that Wynn intentionally misused pain medication before ever taking OxyContin. And he continued with a similar pattern of abuse after obtaining OxyContin. In addition, he hid his abusive habits and obtained the drug through improper doctor shopping and illegal street purchases. Further, Wynn's wife and administratrix of his estate assisted and enabled the decedent to abuse OxyContin by fraudulently obtaining prescriptions for her husband to abuse. Finally, the medical reports indicate that, contrary to the plaintiff's claims, his death was not caused by ingestion of OxyContin but by the abuse of other substances.

G. Amy Foister

Amy Foister ("Foister") is a 58-year old resident of Manchester, Kentucky. She was employed as a welder until she sustained a back injury in March 1972. In addition, she claims that she was struck by an automobile in 1994 or 1995 at a SuperAmerica gas station and that she incurred additional injuries related to another automobile accident and slip and fall after this date. However, it appears that the latter two accidents were fabricated.

To treat her pain, Foister was prescribed, at various times, Valium,[14] Empirin/Codeine,[15] Tylenol/Codeine,[16] Tylox, and Lorcet. Foister received her first OxyContin prescription in July 2000. (Foister Depo. at 33, 36.) She testified that, due to her concerns with the medication, she read the warnings contained in the product literature from the pharmacy. In March 2001, her doctor refused to write any more OxyContin prescriptions due to the "misuse of the meds in our community." [Record No. 168, Ex. 14] In lieu of OxyContin, he prescribed her valium and Lortab. (Foister Depo. at 58.) Foister apparently discontinued her use of OxyContin in March of 2001 and experienced some symptoms of withdrawal for a three to four week period. However, the uncontroverted testimony of the plaintiffs' and defendants' experts indicates that, contrary to her original claims, Foister was not "addicted" to OxyContin.

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14 Valium is a Schedule III narcotic containing diazepam.

15 Empirin/Codeine is a Schedule III narcotic containing codeine and aspirin.

16 Tylenol/Codeine is a Schedule III narcotic containing codeine and acetaminophen.

H. Gus D. Robbins, Sr.

Gus Robbins, Sr. ("Robbins") died on December 19, 1999 at 46 years of age as a result of a lethal injection of cocaine and oxycodone. [Record No. 174, Ex. 1] At the time of his death, Robbins had an extensive criminal history which included malicious wounding of a police officer, assault, criminal mischief, terroristic threatening, conspiracy to possess, sale and deliver cocaine, possession of cocaine, possession of drug paraphernalia, unlawful taking, contributing to the delinquency of a minor, criminal trespassing, as well as a host of other convictions. His numerous civil actions also reflect that Robbins was prone to perjury.

Suit was filed on his behalf by Robbins' daughter, Shelley Robbins Carroll, the administratrix of his estate. Robbins first received opiate analgesics in 1996 to treat kidney stone pain. He received Percocet, Percodan, Tylenol/Codeine, and Vicodin.[17] [Record No. 174, Ex. 16] During the next several years, numerous doctors denied his requests for narcotic pain killers, noting his "drug seeking behavior." [Record No. 174, Exs. 18, 19, 20, 21, 31] In 1992, Robbins pled guilty to federal charges of violating mine safety standards and conspiracy. [Record No. 174, Ex. 24] In 1994, cocaine was found in a drug test required as part of his probation. [Record No. 174, Ex. 25] He was later arrested for possession of cocaine. In March 1995 Robbins failed another drug test. [Record No. 174, Ex. 27] In 1997 he was arrested for possession of marijuana and drug paraphernalia. [Record No. 174, Ex. 28]

Robbins was first prescribed OxyContin in January 1999, following pain from ankle surgery performed in October 1998. [Record No. 174, Ex. 29] Ten days after receiving his

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[17] Vicodin is a Schedule III narcotic containing hydrocodone and acetaminophen.

initial prescription, he returned to the same doctor for another prescription. The doctor refused because he felt Robbins was displaying drug seeking behavior and barred Robbins from returning to his clinic. [Record No. 174, Ex. 32] Following this setback, Robbins sought OxyContin from Dr. Sawaf (discussed *supra*).

Even Dr. Sawaf, one of the most renowned OxyContin distributors in Eastern Kentucky, refused to give Robbins a prescription because Dr. Sawaf noted that "[f]rankly, he was seeking drugs." [Record No. 174, Ex. 33] However, Robbins was able to obtain the drug from other sources. From this time, until his death, Robbins engaged in doctor shopping to obtain overlapping OxyContin prescriptions from any doctor that would write them. [Record No. 174, Exs. 30, 36, 37, 38, 39, 40, 41] During this time he also received prescriptions for Tylox, Demerol, and Vicodin.

In the last month of his life, Robbins began taking OxyContin intravenously. (Carroll Depo. at 39, 68.) He sometimes obtained OxyContin from drug dealers. (Answer Interr. 7.) In the days before he died, his arm was so swollen from drug injections that he could hardly bend it. [Record No. 174, Ex. 47] The death certificate lists the cause of death as injection of cocaine and oxycodone. [Record No. 174, Ex. 1] Robbins did not have the level of opiate in his blood necessary to qualify as a lethal amount. He had .17 mg./L instead of the normal toxic range of .2 mg./L - 5.0 mg./L. (Nicholas Aff. at ¶ 9) Robbins' blood, however, did contain a lethal amount of cocaine (.08 mg./L). (Nicholas Aff. at ¶¶ 4, 5.) Moreover, cocaine typically causes death through its effect on the heart, while OxyContin would typically cause death through the

respiratory system. [Record No. 174, Ex. 50] In this case, the death certificate noted a secondary cause of coronary artery disease.

II. STANDARD OF REVIEW

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A dispute over a material fact is not "genuine" unless a reasonable jury could return a verdict for the nonmoving party. That is, the determination must be "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

"Once a moving party has met its burden, 'its opponent must do more than simply show that there is some metaphysical doubt as to the material facts.' " *Keeneland Ass'n, Inc. v. Earnes*, 830 F.Supp. 974, 984 (E.D.Ky. 1993), (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). The moving party bears the initial burden of informing the court of the basis for its motion and identifying those portions of the record that establish the absence of a genuine issue of material fact. *Chao v. Hall Holding Co., Inc.*, 285 F.3d 415 (6th Cir. 2002).

If the movant satisfies this burden, the non-movant must go beyond the assertions made in the pleadings and come forward with specific evidence to demonstrate that there is a genuine

issue of material fact. *Id.* The nonmoving party cannot rely upon the assertions in its pleadings; rather, that party must come forward with probative evidence, such as sworn affidavits to support its claims. *Celotex*, at 324. However, the trial court does not have a duty to search the entire record to establish that it is bereft of any genuine issue of material fact. *In re Morris*, 260 F.3d 654 (6th Cir. 2002). Rather, the nonmoving party has an affirmative obligation to direct the court's attention to those specific portions of the record upon which it seeks to rely to create genuine issues of material fact. *Id.*

In making this determination, the Court must review all the facts and the inferences drawn from those facts in the light most favorable to the nonmoving party. *Matsushita*, 475 U.S. at 587. Additionally, a federal court sitting in diversity must apply the law of the forum state to the claims asserted. *Moore v. Coffey*, 992 F.2d 1439 (6th Cir. 1993).

III. LEGAL ANALYSIS

Purdue makes four general arguments in support of its motions for summary judgment. First, it argues that the plaintiffs cannot demonstrate causation. Second, it asserts that public policy should preclude a plaintiff from recovering in tort based upon his own illegal conduct. Third, it argues that the learned intermediary doctrine should bar the plaintiffs' claims. And finally, it argues that many of the claims are barred by the statute of limitations. Abbott separately argues that its actions were not causally related to the plaintiffs' alleged harm. Each of these arguments will be addressed in turn.

A. Causation

Kentucky has adopted the "substantial factor test" in evaluating legal causation. *Pathways, Inc. v. Hammons*, 113 S.W.3d 85, 91-92 (Ky. 2003).

> In order to be a legal cause of another's harm, it is not enough that the harm would not have occured had the actor not been negligent. . . . This is necessary, but it is not of itself sufficient. The negligence must also be a substantial factor in bringing about the plaintiff's harm. The word "substantial" is used to denote the fact that the defendant's conduct has such an effect in producing the harm as to lead reasonable men to regard it as a cause, using that word in the popular sense, in which there always lurks the idea of responsibility, rather than in the so-called "philosophic sense," which includes every one of the great number of events without which any happening would not have occurred. Each of these events is a cause in the so-called "philosophic sense," yet the effect of many of them is so insignificant that no ordinary mind would think of them as causes.

Id. at 92 (quoting Restatement (Second) of Torts, § 431 cmt. a (1977)). Thus, the substantial factor test limits actual causation to Kentucky's definition of legal causation. Relying upon this definition, Purdue argues that its actions and product were not the proximate cause of the plaintiffs' alleged harms for those plaintiffs that used the drug illegally.[18] Kentucky has adopted a comparative negligence standard, however. *See* KRS § 411.182. Thus, the plaintiffs need not show that Purdue was responsible for all, or even most, of their alleged harm. However, alteration of a product results in a different conclusion.

As the Supreme Court of Kentucky determined in *Monsanto Co. v. Reed*, 950 S.W.2d 811 (1997), "a manufacturer is not liable when the injuries result from the mutilation or alteration of the [product]. Such intervening conduct severs any causal connection between the product and

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[18] Purdue also argues that the proximate cause of the death of the deceased Plaintiffs', *i.e.*, Robbins and Wynn, was their illegal use of cocaine. As discussed *supra*, this argument is uncontradicted and does not require further discussion.

the injury." *Id., citing, Collins Co. v. Rowe*, 428 S.W.2d 194 (Ky., 1968). Here, seven of the eight plaintiffs (Johnny Wynn, George Allen Saylor, James Presley Craig, Jr., Rodney Dale Howard, Michael L. Daniels, Robin D. Griffin, and Gus Dale Robbins, Sr.) intentionally altered the OxyContin pills and used them in an illegal and unauthorized manner.[19] These plaintiffs either chewed, snorted or injected their pills, as discussed *supra*. These plaintiffs also overdosed the drug with regularity. Further, they clearly ignored the directions that accompanied OxyContin prescriptions. At the relevant times, the package insert for OxyContin stated, in bold letters:

> WARNINGS
> OxyContin . . . TABLETS ARE TO BE SWALLOWED WHOLE, AND ARE NOT TO BE BROKEN, CHEWED OR CRUSHED. TAKING BROKEN, CHEWED OR CRUSHED OxyContin TABLETS COULD LEAD TO THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY TOXIC DOSE OF OXYCODONE.

[Record No. 149, Ex. 19 (emphasis in original)] The warning was repeated later in the insert. Indeed, most of the plaintiffs admitted that they knew that altering the pills could be dangerous.

OxyContin, as approved for use by the FDA, is not unreasonably dangerous when used as directed. Like any drug, however, there are possibilities for abuse. Even "mild" drugs such as aspirin and acetaminophen can be dangerous if used improperly. Such drugs, however, are not unreasonably dangerous simply because they may be harmful if ingested in significant quantities or ingested in an illegal manner. The seven plaintiffs who improperly altered the pills fundamentally changed the characteristics of OxyContin. In effect, they created a different drug. Moreover, in most instances their alteration also included significant overuse of the pills.

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[19] Foister was the only plaintiff not involved in the illegal alteration and use of OxyContin.

The plaintiffs have presented no proof to suggest that the drug would have been unreasonably dangerous absent its illegal alteration. Indeed, the drug's FDA approval indicates that OxyContin is reasonably safe when used as directed. Therefore, the plaintiffs have not demonstrated that OxyContin is the proximate cause of addiction and withdraw symptoms for people using the drug illegally. The proximate cause of any alleged injury in such circumstances is the alteration and/or abuse of the drug, not the drug itself. Thus, the Court finds the holding of *Monsanto, supra*, to be controlling with respect to Johnny Wynn, George Allen Saylor, James Presley Craig, Jr., Rodney Dale Howard, Michael L. Daniels, Robbin D. Griffin, and Gus Dale Robbins, Sr., or their representatives.

B. Public Policy

Purdue argues that, as a matter of public policy, the seven plaintiffs who violated the law in their use of OxyContin should not be able to recover. In Kentucky, a plaintiff may not recover in a legal or equitable proceeding when the basis for such an action rests on their own illegal conduct. *Miller v. Miller*, 296 S.W.2d 684, 688 (Ky. 1956); *see also* 1A Corpus Juris Secundum, Actions § 29 ("[a]s a general rule, a person cannot maintain an action if, in order to establish his cause of action he must rely, in whole or in part, on an illegal or immoral act or transaction to which he is a party"); 1 Am. Jur. 2d Actions § 45 ("[t]he courts refuse to aid those whose cause of action is based on their own illegal conduct").

Other courts have prohibited recovery in prescription drug cases based upon the plaintiff's illegal use of the drug. For example, in *Orzel v. Scott Drug Co.*, 537 N.W.2d 208 (Mich. 1995), a plaintiff claimed that a pharmacist had negligently provided him with

prescriptions for Desoxyn, a Schedule II controlled substance, by failing to ask for identification and not allowing a sufficient interval between filling prescriptions. *Id.* at 210. Plaintiff used the pills for their mind-altering characteristics. He obtained the pills through co-workers and illegal prescriptions under various names that were filled by the defendant. *Id.* at 210-11. The plaintiff became addicted to the drug and began taking 8 to10 pills a day. *Id.* at 211.

The *Orzel* court explained the reasons for refusing to allow a plaintiff to recover based upon his illegal conduct, indicating that:

> [f]irst, by making relief potentially available for wrongdoers, courts in effect would condone and encourage illegal conduct. Second, some wrongdoers would be able to receive a profit or compensation as a result of their illegal acts. Third, and related to the two previously mentioned results, the public would view the legal system as a mockery of justice. Fourth, and finally, wrongdoers would be able to shift much of the responsibility for their illegal acts to other parties.

Id. at 213 (citations omitted). The court held that even when a plaintiff seeks only compensation, rather than profit, the plaintiff should not be able to recover based upon his illegal acts. *Id.* Similarly, when both parties participated in illegal conduct, courts hold the view that "it is better to leave the parties where [the court] finds them." *Id.* (citation omitted). Accordingly, the *Orzel* court refused to allow the plaintiff to recover.

A similar result was reached in *Pappas v. Clark*, 494 N.W.2d 245 (Iowa Ct. App. 1992). In *Pappas*, the plaintiff was addicted to cocaine and prescription drugs. After his death from an overdose, his estate brought suit against his doctor and pharmacist. His estate claimed that the pharmacy should have warned other pharmacies that the plaintiff was attempting to procure prescription drugs by using fraudulent prescriptions. *Id.* at 246. The court noted the distinction

between lawful activities regulated by statute and activities that are entirely prohibited by law, noting that

> when the plaintiff has engaged in activities prohibited, as opposed to merely regulated, by law, the courts will not entertain the suit if the plaintiff's conduct constituted a serious violation of the law and the injuries for which he seeks recovery were the direct result of that violation. In this latter instance recovery is denied, not because the plaintiff contributed to his injury, but because the public policy of this State generally denies judicial relief to those injured in the course of committing a serious criminal act.

Id. at 248 (quoting *Barker v. Kallash*, 468 N.E.2d 39, 41 (N.Y. 1984)). Accordingly, the *Pappas* court held that the plaintiff's cause of action was barred by his illegal conduct.

This Court whole-heartedly agrees with these authorities. As Kentucky courts have similarly relied on such public policy concerns in denying recovery for illegal acts, the seven plaintiffs that procured and used OxyContin illegally may not recover in this action. These parties, Johnny Wynn, George Allen Saylor, James Presley Craig, Jr., Rodney Dale Howard, Michael L. Daniels, Robbin D. Griffin, and Gus Dale Robbins, Sr. (or their representatives), are left with the dilemma which they created. Because they must inevitably rely on their illegal actions to establish their claims, their claims should be denied in the first instance.

C. The Learned Intermediary Doctrine

The gravamen of the plaintiffs' complaint is that Purdue failed to adequately warn of the dangers of OxyContin. As this action involves a dangerous prescription drug, it is governed by the rules of strict liability. Kentucky has adopted the language of Restatement (Second) of Torts § 402A (1965) in adjudicating strict liability cases. *Dealers Transport Co. v. Battery Dist. Co.*, 402 S.W.2d 441 (Ky. 1965). Comment k to that section notes that:

> [t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, . . . many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

When applying Comment k to Kentucky law, "the manufacturer's liability is limited to . . . warning defects, where a manufacturer's failure to market a drug or vaccine without adequate warnings of its dangers renders the product defective." *Snawder v. Cohen*, 749 F.Supp. 1473, 1476 (W.D. Ky. 1990).[20]

The learned intermediary doctrine provides that once a drug manufacturer has warned physicians of the dangers of the drug, the pharmacy's liability is cut off by the physician's knowledge. *See* Restatement (Third) of Torts, § 6, cmt. b; *see also* Lloyd C. Chatfield, Note, *Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule?*, 82 Ky. L.J. 575 (1994). The main difference between the learned intermediary doctrine and traditional application of strict liability is that the learned intermediary doctrine provides for warnings to physicians in lieu of warning patients directly. In this case, Purdue argues that it

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[20] As the defendants correctly note, the crucial question raised by any unavoidably unsafe product is whether the manufacturer provided an adequate warning. If accompanied by an adequate warning, "a desirable but unsafe product is not unreasonably dangerous." Restatement (Second) of Torts, § 402A, comment k (1965). The undisputed facts of this case demonstrate that Purdue provided extensive and adequate warnings to physicians as well as ultimate, intended consumers of the product. These warnings compel a finding that the product was not unreasonably dangerous as a matter of law.

warned prescribing physicians of all relevant side-effects and possible abuses. Thus, if the learned intermediary doctrine applies, the defendants' liability is cut-off by the doctor's knowledge.

Neither Kentucky courts, nor the Kentucky legislature has expressly adopted the learned intermediary doctrine. However, one case has predicted that Kentucky would apply the doctrine, noting Kentucky courts' concern with issues of superceding causes in products liability cases. *Clark v. Danek Medical, Inc.*, No. 3:94CV-635-H, 1999 U.S. Dist. LEXIS 4480 at *15 (W.D. Ky. March 29, 1999).

In *Snawder*, however, the court declined to apply the doctrine. The court did not rule out using the doctrine, however, merely noting that "[w]hile [the manufacturer] may not have had a duty to warn plaintiff or her mother directly, an adequate warning to their physician entails more the [sic] 'prescribing information.'" *Snawder*, 749 F.Supp at 1480. Indeed, the doctrine was not specifically addressed in *Snawder*. Moreover, *Snawder* involved use of the polio vaccine and courts have created a limited exception to the learned intermediary doctrine for mass immunization programs. Chatfield, 82 Ky. L.J. at 576; *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977). Additionally, several courts in other jurisdictions have applied the learned intermediary doctrine. *Beyette v. Ortho Pharmaceutical Corp.*, 823 F.2d 990, 993 (6th Cir. 1987); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *McPheron v. Searle Lab., Inc.*, 888 F.2d 31, 32 (5th Cir. 1989); *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 79 (1st Cir. 1992); *Sterling Drug Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966); *see generally*, Chatfield, 82 Ky. L.J 575.

This court agrees with *Clark* in concluding that Kentucky will likely adopt the "learned intermediary doctrine," as the Restatement (Third) of Torts and numerous other jurisdictions have done, due both to concerns regarding superceding liability in products liability cases and the sound public policy supporting the doctrine. The doctrine ensures that the party most closely connected to the patient and most informed about the particular circumstances of the patient's health passes the relevant information and warnings on to the patient. Indeed,

> only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.

Restatement (Third) of Torts, § 6, cmt. b.

The lengthy and technical warnings provided by pharmaceutical manufacturers are much less useful to patients than the considerate, patient-specific instructions offered by physicians. Physicians are in the best position to determine whether the patient understands the benefits and risks and thus is in the best position to provide the necessary warnings. When it is clear that a patient does not understand the risks involved, the physician can explain them in a different manner until it is clear that the patient comprehends the potential complications.

Pharmaceutical companies, on the other hand, have no direct contacts with patients. Indeed, in many instances the patients may not be able to read the printed warnings provided by pharmaceutical companies, either because they cannot read English or because they cannot read at all. In sum, the physician is in the best position to pass on relevant risks. Thus, a

pharmaceutical company must simply ensure that the physician is made aware of the known risks. Doing so absolves it of liability for failure to warn.

At times relevant to this case, the package insert for OxyContin stated, in bold letters:

> WARNINGS
> OxyContin . . . TABLETS ARE TO BE SWALLOWED WHOLE, AND ARE NOT TO BE BROKEN, CHEWED OR CRUSHED. TAKING BROKEN, CHEWED OR CRUSHED OxyContin TABLETS COULD LEAD TO THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY TOXIC DOSE OF OXYCODONE.

[Record No. 149, Ex. 19 at 3 (emphasis in original)] Later in the insert it warned that "*[i]t must be remembered that OxyContin tablets cannot be crushed or divided for administration.*" [Record No. 149, Ex. 19 at 5 (emphasis in original)] The insert further counseled that OxyContin was a "common target for both drug abusers and drug addicts." [Record No. 149, Ex. 19 at 6]

The insert warned against combining OxyContin "with alcohol, other opioids or illicit drugs which cause central nervous system depression." [Record No. 149, Ex. 19 at 5] Finally, the insert provided that:

> 1. Patients should be advised that OxyContin tablets were designed to work only if swallowed whole. They may release all their contents at once if broken, chewed or crushed, resulting in the risk of overdose.
> . . . .
> 3. Patients should be advised not to adjust the dose of OxyContin without consulting the prescribing professional.
> . . . .
> 5. Patients should not combine OxyContin with alcohol or other central nervous system depressants (sleep aids, tranquilizers) except by the orders of the prescribing physician, because additive effects may occur.
> . . . .

7. Patients should be advised that OxyContin is a potential drug of abuse. They should protect it from theft, and it should never be given to anyone other than the individual for whom it was prescribed.

[Record No. 149, Ex. 19 at 4]

The insert also clearly warned of the possibility of withdrawal symptoms, stating that:

> Physical dependence results in withdrawal symptoms in patients who abruptly discontinue the drug or may be precipitated through the administrations of drugs with opioid antagonist activity . . . . If OxyContin is abruptly discontinued in a physically dependent patient, an abstinence syndrome may occur. This is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia and mydriasis. Other symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate or heart rate.
>
> If signs and symptoms of withdrawal occur, patients should be treated by reinstitution of opioid therapy followed by a gradual, tapered dose reduction of OxyContin combined with symptomatic support . . . .

[Record No. 149, Ex. 19 at 4] It further provided:

> When the patient no longer requires therapy with OxyContin tablets, patients receiving doses of 20-60 mg./day can usually have the therapy stopped abruptly without incident. However, higher doses should be tapered over several days to prevent signs and symptoms of withdrawal in the physically dependent patient. The daily dose should be reduced by approximately 50% for the first two days and then reduced by 25% every two days thereafter until the total dose reached the dose recommenced for opioid naive patients . . . . Therapy may then be discontinued.
>
> If signs of withdrawal appear, tapering should be stopped. The dose should be slightly increased until the signs and symptoms of opioid withdrawal disappear. Tapering should then begin again but with longer periods of time between each dose reduction.

[Record No. 149, Ex. 19 at 8]

Thus, OxyContin's insert clearly set forth the potential dangers of the drug and the best manner in which to minimize those dangers. Even if the patients did not read all of the inserts, their physicians had the ultimate responsibility to do so and to pass that information on to the patients when prescribing OxyContin. Indeed, it appears that plaintiffs were generally aware of the dangers of OxyContin. Presumably, their physicians passed those warnings on to them, although it is also possible that the patients learned of the warnings directly from the literature that accompanies OxyContin. Accordingly, any cause of action for failure to warn would lie with the physicians. Based on the facts in this case, however, it does not appear that any physician (with the exception of Dr.Sawaf) breached that duty or other relevant responsibility owed to a particular plaintiff. In summary, application of the learned intermediary defense bars the claims of all plaintiffs to this action.

D. Statute of Limitations

Purdue argues that the claims of Craig, Howard, Griffin, Saylor, and Daniels are also barred by the statute of limitations. In Kentucky, personal injury actions must be filed within one year from the date of injury. KRS § 413.140(1)(a). The cause of action accrues when the potential plaintiff becomes aware of his injury and the cause of that injury. *Perkins v. Northeastern Log Homes*, 808 S.W. 2d 809, 819 (Ky. 1991). Lack of knowledge of the full extent of one's injuries, however, does not toll the statute of limitations. *The Louisville Trust Co. v. Johns-Manville Products Corp.*, 580 S.W.2d 497, 450 (Ky. 1979).

In this case, Purdue asserts that the alleged injury and cause of that injury were known to these five plaintiffs more than a year before they filed suit. By November 1999, Craig

believed that he was addicted to OxyContin. (Craig Depo. at 24, 31-32, 51-53.) Howard testified that he was using significant amounts of OxyContin by February or March 2000. (Howard Depo. at 22, 26, 28-29.) Daniels testified that he believed he was addicted to OxyContin in early 1998. (Daniels Depo. at 31-32.) Griffin testified that she had been addicted to oxycodone-based drugs since 1994 and stated that she sought out OxyContin in November 1999 to satisfy her addiction. (Griffin Depo. at 37, 55-57, 68.) Finally, Saylor testified that he became addicted to OxyContin sometime before April 2000. (Saylor Depo. at 39, 73.) Thus, five of these plaintiffs were aware of their alleged addiction to OxyContin more than a year before the June 21, 2001 filing of their complaint. Therefore, in addition to the reasons discussed *supra*, the claims of these five plaintiffs are barred by the statute of limitations.

E. Abbott's Motion for Summary Judgment

Abbott was involved in the marketing of OxyContin. It argues that the plaintiffs cannot establish a causal link between their alleged injuries and Abbott's marketing. Abbott points out that it did not market OxyContin to any of the plaintiffs' physicians until *after* they had first been prescribed OxyContin. Thus, Abbott clearly was not involved in the causal chain of the plaintiffs' alleged injuries and is entitled to summary judment. The Court agrees with Abbott's argument and finds that lengthy discussion of this point is not necessary.

IV. CONCLUSION

For the reasons discussed herein, it is **ORDERED** as follows:

(1) plaintiff Amy Foister's motion to file a response out of time [Record No. 182] is **GRANTED** and the response attached to that motion **SHALL** be deemed filed this date;

(2) the Purdue defendants' Reply, attached to its response to plaintiff Amy Foister's motion to file a response out of time [Record No. 185], **SHALL** be deemed filed this date;

(3) the Purdue defendants' motion for leave to file a sur-Reply in opposition to the plaintiff's reply [Record No. 192] is **GRANTED**;

(4) the Purdue defendants' motions for summary judgment [Record Nos. 125, 127, 148, 159, 162, 167, 173] are **GRANTED**;

(5) defendant Abbott's motion for summary judgment [Record No. 132] is **GRANTED**;

(6) All other pending motions [including Record No. 140], are **DENIED** as moot;

(7) This is a **FINAL** and **APPEALABLE** order; and

(8) This case is **STRICKEN** from the Court's active docket.

This 30th day of December, 2003.

Signed By:
Danny C. Reeves DCR
United States District Judge